



Sample Collection

Sample Number:	2340	Sample Class:	Normal Everyday Sam	Sampling District:	CHI-DO	Status:	In Progress	Modif Count #:	
Collector:	Rogers, Sylvia H	Collection Date:	09/25/2000	Lot Size:	125CS/12BTLs/100 TAB				
Sample Origin:		Sample Basis:		Sample Type:	Documentary				
FIS Sample Number:	00	Episode Number:		Related Sample:		Compliance Number:			
Sample Description:	Sample consists of 3 photographs and copies of records documenting interstate commerce and cGMP deficiencies for Wlaprin A								
Collection Reason:	Collected during EI of dealer, dated 9/20-25/2000 to document interstate commerce and cGMP deviations. No analysis needed.								
Collection Remarks:	See EIR of Dealer and FDA-483, dated 9/20-25/2000 for more information. Product description continued ***non-flexible plastic								
Associated Firms									
Resp Firm Type:	Dealer	FEI Number	B	Firm Type		Firm Name		Add	Delete
<input type="checkbox"/> Dealer is Consumer		3000901032		Dealer		Wlaprin Pharmaceutical, 30			
		3000901032		IngredientSupplier		Woleske Chemical, 100 W. M			
Product									
Product Code:	60	L	B	A	05	B	Brand Name:	Wlaprin Arthritis Formula	
Product Name:	Aspirin (Analgesic); Human - Non/Rx Combination In					Product Description:	Aspirin tablets packed in clear*** see remarks		
Product Label:	Finished product labeled in part "***WLAPRIN ARTHRITIS FORMULA 500 Tablets*** Active ingredients: Acetylsalcylic Acid...								
Documents Obtained Manufacturing Codes Sample Flags									



Sample Collection

Sample Number:	2340	Sample Class:	Normal Everyday Sam	Sampling District:	CHI-DO	Status:	In Progress	Modif Count #:	
Collection Method:	Copies of records collected during EI of Dealer, dated 09/20-25/2000. Photographs taken 09/23/2000.								
State:	L	County:	COOK	Country of Origin:	United States				
Estimated Value:	\$4,500.00	Sample Cost:	\$0.00	Payment Method:	No Charge	Receipt Issued:	None		
Carrier Name:	Roadway	Date Shipped:	06/16/2000	Consumer Complaint Number:		Recall Number:			
How Prepared:	All records and photographs identified as below and submitted to Supervisory Investigator. Negatives and extra photos placed in 525								
Collector's ID On Package/Document:	"DOC 2340 9/25/00 SHR"			Collector's ID On Seal:	"DOC 2340 9/25/00 Sylvia H. Rogers"				
Sample Delivered To:		Sample Delivered Date:							
CR & Records Sent To FACTS Org:	CHI-DO	Storage Requirement:							
CR & Records Sent To Non FACTS Org:		Food Canning Establishment:		<input type="checkbox"/> 704 (d) Sample					
Dairy Permit Number:		CRx/DEA Schedule:		<input type="checkbox"/> 702 (b) Portion Collected					
National Drug Code:									
Collection PACs									
PAC Code	Description								
56002	DRUG PROCESS INSPECTIONS(DPI)			Add					
				Delete					
FACTS Org? Physical Sample Sent To									
<input checked="" type="checkbox"/>				Add					
<input type="checkbox"/>				Delete					
<input type="checkbox"/>									

 Sample Flags

Sample Flags

Sample Flag



Remarks

301(k) Sample

OK

Add

Delete

 Documents Obtained

Document

Document
Type



Document
Number

Document
Date

Remarks

OK

Add

Delete

Affidavit

1

09/25/2000

Affidavit signed by Robert Wilson, Presid

Invoice

2

06/16/2000

Invoice no. 2346 dated 06/16/2000 from

Bill of Lading

3

06/16/2000

Bill of lading no. 124679 dated 06/16/200

 Manufacturing Codes

Manufacturing Codes

Manufacturing Code

Exp Date

"Lot 25C83" (Finished Product)

8/06

"Batch 5564" (Active Ingredient)

8/02

OK

Add

Delete

**United States Food and Drug Administration
Collection Report
For Sample Number: 2340**

This is an accurate reproduction of the original electronic record as of 11/07/2003

Flag	Flag Remarks				
301(k) Sample					
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Compliance	Documentary	00908358	In Progress
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3000901032	09/25/2000	60LBA05	Dealer	56002	8
Compliance Num	Country of Origin				
Related Smpl Number	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt
	2	CHI-DO			
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
No				Wilaprin Arthritis Formula	

Product Description

Aspirin tablets packed in clear***see remarks

Product Label

See continuation

Reason for Collection

Collected during EI of dealer, dated 9/20-25/2000 to document interstate commerce and cGMP deviations. No analysis needed

MFG Codes

"Lot 25C83" (Finished Product) 8/06
"Batch 5564" (Active Ingredient) 8/02

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
Wilson Pharmaceutical	300 Riverside Chicago, IL 60606 US	Dealer	3000901032	
Woleske Chemical	100 W. Main Kansas City, MO 64111 US	Ingredient	3000901033	
		Supplier		

Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
125 CS/12 BTLS/100 TAB	\$4,500	None		06/06/1999

Description of Sample

Sample consists of 3 photographs and copies of records documenting interstate commerce and cGMP deficiencies for Wilaprin Arthritis Formula

Method of Collection

Copies of records collected during EI of dealer, dated 09/20-25/2000. Photographs taken 09/23/2000.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

"DOC 2340 9/25/00 SHR"

Collector's Identification on Seal

"DOC 2340 9/25/00 Sylvia H. Rogers"

Samples Delivered To

Date Delivered

Orig C/R & Records To
CHI-DO

**United States Food and Drug Administration
Collection Report
For Sample Number: 2340**

This is an accurate reproduction of the original electronic record as of 11/07/2003

Lab w/Split Sample Lab

Document Number	Document Date	Document Type	Document Remarks
1.	09/25/2000	Affidavit	Affidavit signed by Robert Wilson, President
2.	06/16/2000	Invoice	Invoice no. 2346 dated 06/16/2000 from Woleske Chemical, Kansas, MO for 1-250 lb drum of Acetylsalicylic Acid, batch 5564
3.	06/16/2000	Bill of Lading	Bill of Lading no. 124679 dated 06/16/2000 from Roadway, Inc. Smith Center Kansas for shipment of 250 lbs of Acetylsalicylic Acid from Woleske Chemical, Kansas City, MO to Wilson Pharmaceutical, Inc. Chicago, IL
4.		Other	Raw Material Inventory Card for Acetylsalicylic Acid Batch no. 5564
5.		Other	Photographs 1-3 of labeling for bulk 250 lb. Drum of Acetylsalicylic Acid, Batch 5564
6.		Other	Wilson Pharmaceuticals Batch Record for Wilaprin Arthritis Formula, lot 25C83 (25 pages) (Page 13, 14 and 15 contain copies of all labeling distributed with lot 25C83)

Remarks

See EIR of dealer and FDA-483, dated 9/20-25/2000 for more information. FDA-483 points 1-12 discuss deviations specific to this product. Product Description continued***non-flexible plastic bottle with white screw on top with yellow stick-on label and black printing. Bottles packed in white, paperboard boxes with black printing. Paperboard boxes packed in brown cardboard boxes with black printing.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
\$0.00	No Charge	No	No	Sylvia H. Rogers

Name of Signer	Date & Time of Signature	Meaning
-----------------------	-------------------------------------	----------------

**United States Food and Drug Administration
Collection Report
For Sample Number: 2340**

This is an accurate reproduction of the original electronic record as of 11/07/2003

Product Label

Finished product is labeled in part: "***WILAPRIN ARTHRITIS FORMULA 500 Tablets*** Active Ingredients: Acetylsalicylic Acid...5000mg, Caffeine...32mg, ***100 Tablets*** Lot 25C83***EXP 8/06*** Wilson Pharmaceuticals, Chicago, IL 60606***". 12 bottles are placed in a case, labeled in part: "***WILAPRIN ARTHRITIS FORMULA*** Wilson Pharmaceuticals*** Lot 25C83***EXP8/06***"

Active ingredient documented is Acetylsalicylic Acid packaged in 250 lb drum, labeled in part: "***Acetylsalicylic Acid, USP*** Batch No 5564*** Use by 8/02*** Woleske Chemical, Kansas City, MO 64111***"

How Prepared

All records and photographs identified as below and submitted to Supervisory Investigator. Negatives and extra photos placed in 525, sealed as below and submitted to Supervisor.